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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/536,716

05/30/2006

Catherine Verfaillie

890003-2003.1

2211

27805

7590

02/24/2010

THOMPSON HINE L.L.P.  
Intellectual Property Group  
P.O. BOX 8801  
DAYTON, OH 45401-8801

EXAMINER

QIAN, CELINE X

ART UNIT

PAPER NUMBER

1636

MAIL DATE

DELIVERY MODE

02/24/2010

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/536,716	<b>Applicant(s)</b> VERFAILLIE ET AL.	
	<b>Examiner</b> CELINE X. QIAN	<b>Art Unit</b> 1636	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 28 October 2009.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 1-20 is/are pending in the application.
- 4a) Of the above claim(s) 1-8, 10-17 and 20 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 9, 18 and 19 is/are rejected.
- 7) ☒ Claim(s) 9 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 25 May 2005 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)                                | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948)                        | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

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### **DETAILED ACTION**

Claims 1-20 are pending in the application. Claims 1-8, 10-17 and 20 are withdrawn from consideration. Claims 9, 18 and 19 are currently under examination.

#### ***Response to Amendment***

#### ***Election/Restrictions***

The restriction requirement was made final in the previous office action mailed on 4/28/09. In response, Applicants further argue that the teaching of Hsieh does not suggest that neural stem cells differentiate in to cells of endodermal or mesodermal lineage. Applicants submit that "MAPC" in the claims is clearly defined by the specification not to read on neural stem cells that are restricted to produce only neural progeny. Moreover, Applicants request that the Examiner provide evidence that hematopoietic stem cells can form cells of all three embryonic germ layers, including hepatocytes and neural cells. Lastly, Applicants argue that the exogenously introduced sequence in WO 01/11011 is not homologously recombined.

In response to the above arguments, the Examiner would like to remind Applicants that the restriction requirement was made final in the previous office action mailed on 4/28/09, and should Applicants disagree with the requirement, Applicants have the right to file a petition under 37 CFR 1.144 for director to review the requirement. In response to the argument that whether MAPC read on neural stem cells as taught by Hsieh, the examiner invites Applicants to point to specific teaching within the instant specification as filed originally that define "MAPC" (abbreviation for "multipotent adult progenitor cell") as stem cells which differentiate into all three embryonic germ layers as alleged by Applicants. Otherwise, the Examiner maintains the position that it read on neural stem cells because the terminology is not restricted to such

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definition as evidenced by Hsieh et al. In response to Applicant's argument whether HSC can differentiate into three embryonic germ layers, Applicant's attention is directed to research publication such as Masson et al. (Stem Cells, 2004, Vol.22, pages 897-907), which discusses potential of HSC therapy in hepatology, and also indicated that HSC participates in neurogenesis (see page 898, 2<sup>nd</sup> col., 2<sup>nd</sup> paragraph, line 10). Moreover, Masson et al. also state that adult mouse neural stem cells can give rise to cells of all germ layers. This further supports the Examiner's position that the MAPC encompasses neural stem/progenitor cells. Lastly, in response to Applicant's argument directed to the disclosure of WO 01/11011, Applicants are reminded that the special technical feature of Group I is MAPC comprising exogenously incorporated sequence. Whether the exogenously incorporated sequence is introduced with homologous recombination or not does not impart a structural difference to the claimed cell. Therefore, for reason given in the previous office action and above, Applicant's arguments are not persuasive.

### ***Claim Objections***

Claim 9 is objected to for depending on non-elected claim 6. This claim is also objected to for using the term "MAPC" which may stand for a number of different words. It is remedial to spell out the entire term.

Applicants did not respond to the objection, this objection is thus maintained for same reason as set forth in the office action mailed on 4/28/09.

### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

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A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 9 and 18 are rejected under 35 U.S.C. 102(a) as being anticipated by Lamming et al (Blood, 2002: 100(11): abstract number 2574).

Claim 9 is drawn to a recombinant MAPC produced by the method of claim 6. This is a product by process claim, which reads on the product, a multipotent adult progenitor cell that comprises exogenously introduced DNA sequence. Claim 18 is drawn to a genetically altered multipotent adult progenitor cell that comprises exogenously introduced DNA.

Lamming et al. disclose multipotent adult progenitor cell comprises transfected with DS-RED expressing plasmid, and long term expression of DS-RED in said cells (see page 655a, 1<sup>st</sup> col., lines 14-16). Therefore, Lamming et al. disclose the instantly claimed invention.

Claims 9, 18 and 19 are rejected under 35 U.S.C. 102(b) as being anticipated by Jahagirdar et al (Blood, 2001. 98(11 part 1): 547a).

Jahagirdar et al. disclose MAPC isolated from b-gal transgenic ROSA26 mice, which is genetically altered MAPC that comprises exogenous DNA (see col.1, line 5). Jahagirdar et al. also disclose that said cells differentiated in vivo in NOD-SCID recipient mice (see col.1, lines 11-26). Therefore, Jahagirdar et al. disclose the instantly claimed inventions.

Claims 9, 18 and 19 are rejected under 35 U.S.C. 102(b) as being anticipated by Furcht et al (WO 01/11011 A2).

Furcht et al. disclose isolated genetically altered MAPC comprising DNA that expresses eGFP. Furcht et al. further disclose said cells differentiate into mesodermal cell types following

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expansion (see for example, page 40, 1<sup>st</sup> paragraph). Therefore, Furcht et al. disclose the instantly claimed invention.

In response to the above rejection, Applicants argue that the present application claims priority to WO 01/11011, with an effective filing date of 8/4/2000. Applicants thus conclude that the cited references cannot serve as prior art.

This argument has been fully considered but deemed unpersuasive. The instant specification is filed as a 371 national stage of PCT/US03/38811, which claims priority to the provisional application 60/429,631, which was filed on 12/27/2002. As such, the earliest priority date for the instant application is 12/27/2002. The instant specification makes reference to WO 01/11011 (see page 1), however, this statement does not make this reference a priority document for the instant application. The oath and declaration filed on 5/30/06 does not identify WO 01/11011 as priority document either. Therefore, the references cited in the 102 (a) and (b) rejections can serve as prior art in view of the priority date being 12/27/2002. As such, the above rejections are maintained.

### ***Conclusion***

No claims are allowed.

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

This application contains claims 1-8, 10-17 and 20, drawn to an invention nonelected with traverse in the reply filed on 2/11/09. A complete reply to the final rejection must include cancellation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.

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A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to CELINE X. QIAN whose telephone number is (571)272-0777. The examiner can normally be reached on 10-6:30 M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christopher Low can be reached on 571-272-0951. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would

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like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Celine X Qian /  
Primary Examiner, Art Unit 1636